UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/564,525	06/25/2006	Emmanuel Kossi Tangni	11016-0056	2042

22902 7590 10/18/2007

CLARK & BRODY
1090 VERMONT AVENUE, NW
SUITE 250
WASHINGTON, DC 20005

EXAMINER	
UNDERDAHL, THANE E	
ART UNIT	**PAPER NUMBER**
1651	

MAIL DATE	DELIVERY MODE
10/18/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/564,525	TANGNI ET AL.	
	Examiner	Art Unit	
	Thane Underdahl	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 July 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to the Applicant's reply received 7-27-07. Claims 1-22 are pending. No claims are withdrawn. No claims are cancelled. Claims 1-4, 12, 14, 20 and 21 have been amended. Claim 22 is new.

Response to Applicant's Arguments— 35 U.S.C § 112

In the response submitted by the Applicant the 35 U.S.C § 112 rejection of claim 1-21 are withdrawn in light of the Applicant's amendment.

Response to Applicant's Arguments— 35 U.S.C § 103

In the response submitted by the Applicant, the 35 U.S.C § 103 (a) rejection of claims 1-15 over Yoshihide et al. and Sasaki et al. with support from Davids and Huwig et al. and Kada et al. were considered but not found persuasive.

The Applicant argues that Yoshihide et al. does not teach the use of a micronized insoluble fiber and even sites Example 2 as support for this assertion. The Applicant asserts wheat germ used by Yoshihide et al. contain only a "very weak fraction" of fibers. However there is no limitation in the claims excluding how the fibers are obtained only that the fibers are insoluble and micronized so this argument is not commensurate in scope with the claim. Furthermore Example 2 does include rice bran as an option, which the Applicant admits contains significant amounts of fiber (Applicant's argument, page 17, paragraph 3 and 4). Indeed Yoshihide et al. even teach in Example 2 that their water-insoluble germ preparations are "aqueous suspensions" instead of solutions. Furthermore, concerning the making of the germ preparations the end product is a suspension of germ, that inherently contains fibers, in distilled water. These germ preparations were filtered through a 0.45 μm filter during the processing. This inherently gives the fibers the size of less than 0.45 μm. There is

no evidence to the contrary that the germ suspensions are devoid of fiber from the centrifugation or filtration. While the Applicant argues that the method of preparation would remove fibers from the filtrate, this argument is merely the argument of counsel and is unsupported by evidence or declarations of those skilled in the art. Attorney argument is not evidence unless it is an admission, in which case, an examiner may use the admission in making a rejection. See M.P.E.P. § 2129 and § 2144.03 for a discussion of admissions as prior art. Counsel's arguments cannot take the place of objective evidence. *In re Schulze*, 145 USPQ 716 (CCPA 1965); *In re Cole*, 140 USPQ 230 (CCPA 1964); and especially *In re Langer*, 183 USPQ 288 (CCPA 1974). See M.P.E.P. § 716.01(c) for examples of attorney statements that are not evidence and that must be supported by an appropriate affidavit or declaration. The Applicant is strongly encouraged to submit an affidavit or supporting documentation from the art-recognized literature to overcome this rejection.

Likewise arguments of council concerning the mechanism of how the fibrous germ of Yoshihide et al. removes the mutagenic agent remain unpersuasive in the absence of an affidavit or supporting documentation from the art-recognized literature supporting the Applicant's argument.

The Applicant argues that Yoshihide et al. or Sasaki et al. do not provide the motivation to remove the fibers from the solution. However the Applicant's attention is drawn to page 9, the last paragraph of Yoshihide et al. that includes an optional filtration step once the fibrous germ preparation is added. Furthermore Sasaki et al. teach that

their fibrous materials derived from plants can be used to remove ("isolate") mutagenic substances from solutions (Sasaki, col 3, lines 1-20).

The Applicant argues that the teachings of Yoshihide that include the use of hydrogen peroxide in their method do not act by adsorption. However the open language of the Applicant's claim by using the word comprising does not exclude the use of hydrogen peroxide in the method.

The Applicant argues that the divergent nature of the two inventions makes combining them improper. However the Examiner respectfully disagrees. As described in the previous rejection and is repeated below both teach the removal of mutagens with fibrous plant extracts.

Furthermore the Examiner would like to point out that the supporting references were used to simply provide support that it is well known in the art that mutagens, including mycotoxins can be removed with plant fibers, but were used for clarification only and that the rejection was made over Yoshihide et al. in view of Sasaki et al.

Also the Applicant argues that Boeira et al. does not correct for the deficiency of Yoshihide et al. However as mention in the previous rejection and repeated below the rejection of 1-21 and now new claim 22 was not to correct the teachings of Yoshihide et al. concerning the fibrous material but to provide motivation to remove mycotoxins from a fermentation process.

Finally the Applicant asserts that the unexpected results of their invention overcome the obviousness rejection. Further, the evidence necessary to overcome a *prima facie* case of obviousness must not only be clear and convincing, but must also

be commensurate in scope with the claimed subject matter. The Examiner asserts that indeed the teachings of Yoshihide et al. do include micronized fibers because of the size of the pores of the filter the fibers passed through (0.45 μm). Clearly Yoshihide et al. does teach the isolation of mycotoxins using micronized fibers and as such the results are not unexpected.

Therefore the rejections stand and are repeated below.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-15 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Yoshihide et al. (EP 0124891 A2. 1984) and Sasaki et al. (U.S. Patent # 4,770,880, 1988) with support from Davids (CoffeeReview, 2000) and Huwig et al. (Toxicology Letters, 2001) and Kada et al. (Mutation Research, 1984).

These claims are drawn to a biological process that comprises the following steps: Absorbing the mycotoxins from liquid dietary medium (**LDM**) by contacting the LDM with micronized insoluble plant fibers and removing said fibers on which the mycotoxins are absorbed. These insoluble plant fibers are derived from dietary plants selected from cereals, leguminosae, culinary plants, fruits or plants derived from the paper industry such as trees, sugarcane, bamboo, or cereal straw. The cereals may be from wheat, barley, oat, corn, millet, rice, rye, sorghum fiber or the malted equivalents of any grain from this list. The fibers may be from apples, pears, grape berries, lupin, soya

bean seeds, tomatoes, peas and coffee. Claim 5 limits that the fibers be microparticles, of which 90% of the total mass of the microparticles are less than or equal to 700 µm in size. Claim 6 further limits that 90% of the microparticles are 200 µm in size. Claim 7 limits that the preliminary step of the method hydrates the fibers. Claim 8 limits that the plant fibers added during the method are 0.1 to 20% by weight per liter of LDM. Claim 9 limits that the LDM is brought into contact with the fibers for a period ranging from a few seconds to 90 minutes. The pH of the LDM contacting the plant fibers is between 1.5 and 7 and the temperature during contact is maintained between 7 and 80 °C. The LDM is selected from beer, mixtures of malt and water and mash of the brewing process, wine, coffee, fruit juices, milk, and glucose syrups. The fibers are removed by filtration at the end of the period of contact. Claims 14 and 15 further limit that the LDM is contacted with the fibers and the fibers are removed by filtration. Also the plant fibers from an integral part of the filtration system.

Yoshihide et al. teach a method to remove mycotoxins such as aflatoxin (Yoshihide et al., page 2, line 5) from LDM such as coffee, tea and fermented products such as bourbon whiskey (page 4, lines 12-15) using micronized insoluble plant fibers (Yoshihide et al., page 16 line 28-30) that are at least less than 0.45 µm in size (Yoshihide et al., page 17, lines 1-5). These fibers inherently absorb mycotoxins as supported by Kada et al. and Huwig et al. (see abstracts of both articles). These fibers are obtained from cereal grains such as wheat, barley malt, rice and soya beans (soybeans). The fibers are hydrated prior to the addition to the LDM (Yoshihide et al., page 11, lines 24-26). And 0.05 to 5 mg of fiber is added to 1mL of LDM or 5% to 500%

by weight of fiber per liter of LDM (Yoshihide et al., page 10, lines 19-23). The fibers are mixed with the LDM for 20 minutes (Yoshihide et al., page 14, lines 13-15) at the temperature is maintained at 70 °C. Since the fibers are mixed directly with LDM like coffee, which has a typical pH range of 4.5 to 5 (as supported by Davids, page 1; 2nd paragraph), Yoshihide inherently meets the pH limitation of claim 10, which is a pH between 1.5 to 7.

What Yoshihide et al. do not teach is the removal of the fiber by filtration. Regardless this would be obvious to one of ordinary skill in the art by the time the invention was made in view of the teachings of Sasaki et al. They teach using powder of fiber rich vegetables such as bamboo sprout, cabbage, spinach, soybean malt and paper products as cellulose to (Sasaki et al. col 2, lines 15-30) to remove mutagenic substances from food (Sasaki et al. col 2, lines 37-40). One of ordinary skill in the art would recognize that these are the same or similar fibrous vegetables used by Yoshihide et al., Huwig et al. and Kada et al. to remove mycotoxins. Since mycotoxins are mutagenic, it would be obvious to use the teachings of Sasaki et al. with those of Yoshihide et al. since they too remove mutagenic substances. It would have been obvious to someone skilled in the art to isolate mycotoxins from LDM using plant fibers. The motivation to isolate the plant fibers from the LDM after they have absorbed mycotoxins comes from Sasaki et al. who teach that use of plant fibers to remove mutagenic substances from food. Since mycotoxins are mutagenics substances and Huwig et al. and Kada et al. and Yoshihide et al. teach that mycotoxins can be removed using the same or similar plant fibers as Sasaki et al. they provide the reasonable

expectation of success. Therefore, it claims 1-12 are prima facie obvious over the combined references of Yoshihide et al. and Sasaki et al.

While neither reference explicitly teaches the remove of the insoluble plant fibers by filtration at the end of the period of contact with the LBM. However it would have been obvious to someone skilled in the art to remove the fiber via filtration since the skilled artisan would recognize that removing insoluble material by filtration is a common and efficient practice.

Also claim 14 and 15 are prima facie obvious over Yoshihide et al. and Sasaki et al. since these two claims deal with making the process of removing mycotoxins with plant fibers continuous and make the fibers integral with the filtration system. M.P.E.P. § 2144.04 V B and E state that is prima facia obvious to make a process integral or continuous absent any showing insight that is contrary to the understandings and expectations of the art.

Therefore, the invention as a whole would have been prima facie obvious at the time of filing in view of the references listed above and as such claims 1-15 are not allowable.

Claims 1-21 remain rejected and new claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yoshihide et al. and Sasaki et al. as applied to claims 1-15 above, and further in view of Boeira et al. (J. Appl. Micro, 2000).

The description and rejection of claims 1-15 are described above in the 35 U.S.C 103(a) rejection over the teachings of Yoshihide et al. and Sasaki et al. Claims 16-21

are drawn to a brewing process where the mycotoxins are absorbed via the method of claim 1. The absorption can take place simultaneously with the mashing step, after the fermentation step or maturing the wort. The fibers that are brought into contact with the brewing process used to absorb the mycotoxins are removed by filtering. The amount of fibers used in the process are 0.5 to 20% by weight of the malt. Claim 21 limits that the plant fibers are introduced into the fermented wort at a rate of 0.05 to 5% by weight based on the total weight of the wort.

As stated in the 35 U.S.C § 103 rejection above Yoshihide et al. and Sasaki et al. teach that it is prima facia obvious to add 5% to 500% by weight of fiber per liter of the liquid such as fermented beverages such as malt (page 10, lines 19-23). And that it is prima facia obvious to filter out the fibers to isolate the mycotoxins from the beverage. While Yoshihide et al. and Sasaki et al. teach the method of claim 1, they do not teach it for a brewing or fermentation process. Regardless this would be obvious to one of ordinary skill in the art by the time the invention was made in view of the teachings of Boeira et al.

Boeira et al. teach that mycotoxins are transferred from grains to wort to beer in a fermentation process (Boeira et al. page 388 col 2 paragraph 3 to page 389 col 1 paragraph 1). Boeira et al. also teach that mycotoxins in food and feed are toxic and hazardous to humans and animals (Boeira et al. page 389, col 1, paragraph 2). It would have been obvious to someone skilled in the art to use the teachings of Yoshihide et al. and Sasaki et al. and use insoluble plant fibers to remove mycotoxins during each of the following steps: to cleans the grain before fermentation begins, during the fermentation

process, when the grain is made into wort, when wort is fermented and after the fermented product is made into beer since Boeira et al. teach that at each of these steps mycotoxins can be found. Furthermore Boeira adds further motivation to remove mycotoxins from the fermentation process since mycotoxins inhibit the growth of yeast (Boeira et al. see abstract) which one of ordinary skill in the art would recognize is a key element to fermentation. The reasonable expectation of success is provided by Yoshihide et al. and Sasaki et al. who successfully teach the removal of mycotoxins from other fermented beverages such as bourbon whisky (Yoshihide et al., page 4, line 13).

While neither teach the rate at which the fibers are introduced into the fermented wort. However the rate at which a substrate is introduced into a continuous process is a result effective variable that would be recognized by one of ordinary skill in the art. Absent any teaching of criticality by the applicant concerning the rate listed in claim 21 it would be *prima facie* obvious that one of ordinary skill would meet the rate limitation of claim 21 by routine optimization (M.P.E.P. § 2144.05 II).

Therefore, the invention as a whole would have been prima facie obvious at the time of filing in view of the references listed above and as such claims 1-22 are not allowable.

In summary no claims, as written, are allowed for this application.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

In response to this office action the applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP § 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 U.S.C. § 102 or 35 U.S.C. § 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending U.S. applications that set forth similar subject matter to the present claims. A copy of such copending claims is requested in response to this Office action.

CONTACT INFORMATION

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thane Underdahl whose telephone number is (571)

272-9042. The examiner can normally be reached Monday through Thursday, 8:00 to 17:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached at (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Thane Underdahl
Art Unit 1651

Leon B. Lankford Jr
Primary Examiner
Art Unit 1651